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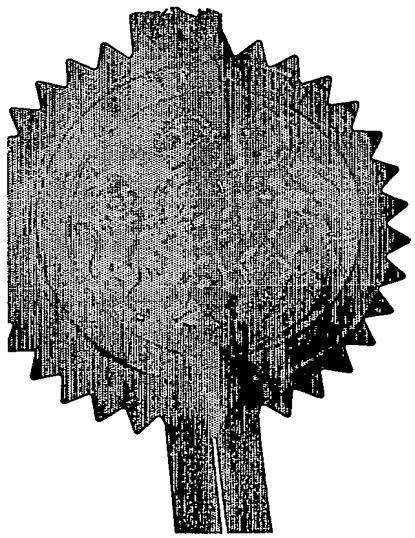

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2. Patent application number *(The Patent Office will fill in this part)* — 0206061.4

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

ANGIOMED GmbH & Co.
MEDIZINTECHNIK KG
Wachhausstrasse 6
D-76227 Karlsruhe
Germany

Patents ADP number *(if you know it)* — 7858574001

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4. Title of the invention

METAL STRUCTURE COMPATIBLE WITH MRI IMAGING, AND METHOD OF MANUFACTURING SUCH A STRUCTURE

5. Name of your agent *(if you have one)* — ~~David Lethem~~

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Hoffmann Eitle
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London WC2A 3LZ

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12. Name and daytime telephone number of person to contact in the United Kingdom: David Lethem, Hoffmann Eitle, 020 7404 0116

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METAL STRUCTURE COMPATIBLE WITH MRI IMAGING, AND METHOD OF MANUFACTURING SUCH A STRUCTURE

FIELD OF THE INVENTION

This invention relates to magnetic resonance imaging and in particular, but not exclusively, to a tubular radially expansible structure, and in particular to such a tubular structure which defines a plurality of expansible rings arranged adjacent one another along the longitudinal axis of the structure, and in which each of the rings defines at least one bridge end and adjacent rings being linked by a bridge extending between adjacent bridge ends on adjacent rings. The invention also relates to a method of manufacturing such a tubular structure, and to a medical guidewire.

Although the present invention has particular usefulness for providing tubular structures in the form of medical stents, it also has applications to implants (for example filters and fluid-flow measuring devices) other than stents. It may also have applications outside the field of medical stents, implants and prostheses. It is particularly of interest for laser-cut prostheses and self-expanding nickel-titanium alloy devices.

BACKGROUND ART

With the advent of magnetic resonance imaging (MRI) techniques, the imaging of soft tissue structures in a non-invasive fashion has become feasible. When a human or animal body is exposed to a strong external time-independent

magnetic field (B_0), the magnetic moments associated with the spins of the exposed atomic nuclei will become aligned with the direction of B_0-field resulting in a total magnetisation to be detected. The direction of this total magnetisation in its equilibrium state is parallel to the direction of the external magnetic field B_0. This equilibrium state, however, is not static but, rather, dynamic because the total magnetisation precesses with the so-called Larmor-frequency about the direction of the B_0-field.

Upon application of a high frequency (HF) signal having a frequency equal to the Larmor-frequency (resonance frequency) and emerging from a direction different to that of the B_0-field, a spin-flip of the nuclei can be observed and associated with the spin-flip, the relaxation time required to relax the spins back to their original alignment with the B_0-field can be measured by means of an external coil being tuned in resonance with the HF-signal.

The angle α by which the spins have been deflected by the HF-signal with respect to the B_0-field direction is proportional to the time period of the HF-signal and the magnitude of the static magnetic field B_0. Subsequent to the spin flip, the total magnetisation precesses about the B_0-field with the angle α, and this precessing motion of the total magnetisation may be recorded by the external coil that is oriented perpendicular to the B_0-field. The coil outputs a voltage signal whose magnitude is proportional to $\sin(\alpha)$, is proportional to the density of the spins and is inversely proportional to the temperature.

If the spins are deflected by an angle α of 90°, a maximum signal response is obtained. Due to the individual spins losing their strict phase-correlation, the recorded signal amplitude decreases exponentially with the relaxation time T_2. Simultaneously, the total magnetisation increases exponentially again in the direction of the B_0-field towards

the equilibrium magnetisation with the relaxation time T_1. By means of magnetic gradient-fields switched on at the correct point in time, it is possible to image the two relaxation times in a grey scale encoded image with spatial resolution.

With the discovery of superconductors having a transition temperature above liquid nitrogen temperature, superconducting magnets have become widely used and thus have rendered MRI-imaging techniques more cost-effective. MRI imaging techniques have so far been predominantly used for imaging soft tissue structures, such as the human brain and other internal organs.

Implants, such as vascular grafts or stents, are predominantly made of biocompatible metals. These metals are still preferred over their polymeric-based competitors. Nickel-titanium alloys are attractive in that they have good fatigue resistance and a memory which brings them to the shape desired upon deployment. Stainless steel is another biocompatible material used for making stents.

There has long been a wish to determine the rate of fluid-flow through the stent lumen as well as the amount of tissue hyperplasia in order to examine the extent of restenosis in each patient. This information would also help stent designers to optimise and improve their stent structures in terms of avoiding restenosis from occurring as well as to help the medical practitioner to exactly determine the extent to which restenosis inside the stent lumen re-occurs after it has been deployed inside the human or animal body in order to specify more precisely those measures for treating the restenosed region in an appropriate and timely manner.

Attempts to MRI-image the blood flow and tissue-ingrowth in metallic vascular implants are prevented, or strongly impaired to say the least, by the ferromagnetic or paramagnetic nature of the metals used or impurities in other

materials which result in artefacts in the images, thus reducing the quality of these images down to levels too low to be useful.

On the one hand, these artefacts are thought to be due to differences in susceptibility between metal and tissue resulting in magnetic fields in proximity of the metallic implant being non-uniform and multidirectional, thus destroying the signal response from the HF-pulse in the proximity of the implant. On the other hand, the wavelength of the HF-signals used is such that the implant is, to a certain degree, impenetrable to the HF-signal, i.e. the penetration of the HF-signal through the implant is impaired. Hence, the image of the implant lumen or the body structure therein has been seriously compromised.

These disadvantages make MRI-imaging techniques not very effective for imaging patency of vascular metallic implants, and consequently, X-ray fluoroscopy with all its known disadvantages (invasive, ionising radiation) is used instead.

WO-A-96/38083 discloses a probe having at least one pair of elongated electrical conductors, preferably disposed parallel to each other within a dielectric material, and having a pair of ends electrically connected to each other. This probe thus formed is, in a preferred use, introduced into small blood vessels of a patient to facilitate determination of arteriosclerotic plaque using an MRI-imaging technique. This probe, however, is electrically conductive along its entire axial length, thus providing a Faraday screen to minimize dielectric losses between the probe and the surrounding material.

US-A-6,083,259 addresses the problem of poor visibility of a lumen within a stent. The stents it discloses generally include a series of co-axially aligned circumferential elements and oriented in separate planes spaced axially from

each other. Each circumferential element includes a wave-like series of curvatures. Each curvature includes a trough, defined as being that portion of each circumferential element which is most distant from an adjacent circumferential element, and a crest, being defined as that portion of each circumferential element that is closest to an adjacent circumferential element. Each gap between two adjacent circumferential elements is spanned by at least one axial element. The axial elements are either tie bars or double-bend links, such as a S-shaped link. Both the stent and the axial elements are made of the same material. The stent can additionally include enhanced density markers which increase the visibility of portions of the stent when viewed with a medical imaging device, such as a fluoroscope.

US-A-5,123,917 discloses an intraluminal vascular graft in which separate scaffold members are sandwiched between two PTFE inner and outer tubes. The ring-like scaffold members are made of stainless steel and are expandable upon application of a radially outwardly extending force from the interior of the inner tube. The vascular graft includes no metallic cross-links adjoining two adjacent scaffold members. It is the PTFE inner and outer tubes which hold the vascular graft together.

Another intraluminal graft for placement in a body lumen is disclosed in US-A-5,122,154. The graft comprises a plurality of stents which may be completely encased in the graft material, the graft material preferably being made of PTFE. In this intraluminal graft, the individual stents are spaced apart axially. The only link between adjacent stents is the PTFE graft material.

EP-A-1 023 609 discloses a stent, said to be compatible with MRI-imaging techniques. The stent consists of a metal skeleton, which is provided with an inductor and a capacitor. Here, the inductor and capacitor may be defined by the

skeleton itself, or may be separate devices attached to the skeleton which are linked in parallel to one another. The inductor and capacitor represent a harmonic oscillator which is tuned in resonance with the HF-signal of a MRI-imaging apparatus.

In case of the skeleton defining the inductor and the capacitor itself, the skeleton may consist of a two or more layered structure, in which the skeleton is made up of a material having a relatively low electrical conductivity, such as platinum, titanium or titanium alloys, or of plastics or carbon fibres, and a second layer having a very high electrical conductivity in comparison with the first layer and representing the inductor and capacitor material, for example gold or silver. The second, highly conductive layer is cut along circumferential paths during manufacture of the stent. This way, the stent structure comprises several inductors which are connected in parallel. The capacitor is formed at one end of the stent structure by cutting through the conductive layer along a relatively short axial path being perpendicular to the cutting paths forming the inductors. In operation, an amplification of the excitation of the nuclei spins by means of the resonance circuit, i.e. the inductor and capacitor, is induced. Therefore, position determination of the stent may be achieved. Furthermore, based on the different excitations inside and outside of the stent, flow rate measurements of the medium flowing through the stent or along the stent is possible. Here, however, the stenting material exhibits poor electrical conductivity and is preferably non-metallic, and there are no cross-links in the mesh-structure of the stent which are entirely severed so that gaps in the mesh-structure would appear.

WO-A-01/32102 discloses a tubular structure having a plurality of meander-shaped rings.

In US-A-5,807,241 a bendable endoscope is disclosed which comprises tube sections so that neighbouring tube sections are completely materially separated from one another via circumferential separating gaps and are only connected to one another by means of a positive fit. By providing an appropriate number of tube sections, a flexible shaft may be formed. The manufacture may be effected by laser-cutting from a rigid tube.

US-A-5,741,327 discloses a radially expandable surgical stent with radiopaque marker elements in the form of rings attached to the ends of the stent. The radiopaque marker elements include tabs which match the contour of receivers provided at both ends of the stent for secure attachment.

SUMMARY

It is an object of the present invention to provide a tubular structure, such as a stent, which allows MRI-imaging of the lumen within the tubular metal structure. It is also another object of the present invention to provide a tubular structure which permits improved determination of the fluid-flow through the lumen of the structure by means of MRI-imaging.

This object is solved by a tubular structure having the features of independent claim 1. Further embodiments are described in dependent claims 2 to 17.

According to one preferred embodiment of the present invention, the bridges linking two adjacent meander-shaped rings together, comprise complementary mating portions as the conductivity break. In case that these mating portions are of the type of male/female form-fitting portions, a rapid connection between two adjacent rings can be accomplished, either manually or by means of a specifically designed machine tool. In another preferred embodiment, these form-

fitting portions may have a frusto-conical shape. If the stent material is cut by a laser with its line of action always being radial to the stent cylinder, a frusto-conical form-fit between the two complementary form-fitting portions is achieved, thereby enhancing the security of attachment and the precision of placement of both complementary form-fitting portions.

In accordance with another preferred embodiment, at least one of the mating portions is encapsulated in a bio-compatible non-conductive adhesive for enhancing the rigidity of the bridge and for providing a conductivity break. This bio-compatible adhesive increases the maximum tensile force the bridge is capable to withstand upon radial expansion of the tubular structure and inhibits the current flow from one end of the implant to the other.

If, according to another advantageous embodiment, at least one of the mating portions comprises an oxide layer as the conductivity break, the bio-compatible adhesive does not necessarily have to be non-conductive. The oxide layer can either be created, as described below, or can be the naturally occurring oxide layer on the surface of the metal.

An oxide layer as the conductivity break is preferred due to the ease of creating the oxide layer on at least one of the mating portions. One way of creating the oxide layer is to radiate one of the mating portions with a laser, thus oxidising the metal surface of that mating portion. Another way is to immerse one of the mating portions in an oxidising agent, such as a Lewis acid, or if the temperature generated during laser-cutting is sufficiently high, then oxidisation may already take place during the laser-cutting step so that the above-described extra steps, e.g. immersing one of the mating portions into an oxidising agent, may be omitted. Depending on the magnitude of the voltage induced by the time-dependent magnetic field in the meander-shaped rings, a

very thin oxide layer may be sufficient, such as the naturally occurring oxide layer on the surface of the metal or a very thin oxide layer created as described above, to prevent current-breakthrough between two mating portions forming the bridge. If the voltage exceeds a certain level, the addition of a non-conductive adhesive may well be suitable to prevent such current-breakthrough.

The exact shape of the outline of each of the mating portions, and the exact shape of the abutment surfaces on them which contact each other, is a matter of design freedom and choice. At the moment, for tubular structures which are stents, it is contemplated to provide the two mating portions as two complementary form-fitting portions one of which is the male mating portion with a mating head portion, and the other one of which is the female mating portion with an arcuate portion, such that the female mating portion comprises a rebated internal abutment surface to receive the corresponding mating head portion.

If the two complementary form-fitting portions forming the bridge are created by a laser-cutting process, in which the laser beam lies on a radius to the cylindrical form of the workpiece, the two mating portions automatically comprise a frusto-conical shape, which further provides a snap-fit inter-engagement of the two mating portions, further helping to accomplish precise positioning and orientation of the two mating portions relative to the tubular structure. Further, if the co-operating surfaces of the two mating portions are both cut with a laser on a radial line of action, then there will tend to be a self-centering and self-aligning effect when one meander-shaped ring is offered up, end-to-end, to the adjacent meander-shaped ring, particularly with self-expanding stent designs.

If a steerable laser is used for laser-cutting, the two form-fitting portions forming the bridge may be shaped such, that

they are inter-locked with each other, such that it is impossible to separate them, either radially or axially, yet such that they are separated themselves by a film of oxide. This can be accomplished by varying an angle of tilt of the laser focus, as one advances the laser beam around the circumference of the connecting portions of two adjacent rings. By doing this, one can create, for example, cuts through the wall thickness which exhibit two frusto-conical zones in one of which the cone tip lies on the axis of the stent cylinder and in the other the cone tip lies outside the stent cylinder, such that the connecting portions are interlocked and not separable. This resembles a jig-saw with alternating tilted abutment surfaces. Due to the laser focus having a certain width, there is a gap between two adjacent bridge ends of the bridge providing sufficient room for the conductivity break therebetween.

It is to be noted that the same effect can be achieved by appropriate emboss preparation of both form-fitting portions when the form-fitting portions were previously cut with a laser on a radial line of action. The emboss preparation aims to impart tilted surfaces on the two form-fitting portions.

In another advantageous embodiment, the length axis of the bridge is not parallel to the longitudinal axis of the tubular structure. Such a bridge with its axis not being parallel to the longitudinal axis of the tubular structure can give the overall structure enhanced flexibility, particularly when the structure is confined within an outer sheath and is advanced along a tortuous path within a body lumen. According to other embodiments of the present invention, the bridge may be meander-shaped or S-shaped for the same reasons.

A particular advantageous embodiment provides a tubular structure whose number of bridges is less than the number of meanders in one circumferential zig-zag ring. In finding an

improved structure well suited for MRI-imaging techniques, one can choose to reduce the number of bridges between two adjacent rings down to a structural minimum. Alternatively, one can use an entirely non-conductive structure, just for the bridges or the stent as a whole.

One supposes that the HF-signal is more likely to penetrate the metallic tubular structure because the tubular structure is no longer seen by the HF-signal as a Faraday cage, and therefore the HF-signal will also cause a spin-flip of the nuclei within the lumen of the tubular structure. Hence, one supposes, less artefacts will occur in the obtained MRI-image of the lumen, thereby facilitating imaging of the matter, such as tissue within the lumen of a body vessel, within the lumen of the tubular structure and determination of fluid-flow therethrough.

A practical minimum number of bridges between adjacent stenting rings is 2 per circumference. The number, however, can be chosen according to the mechanical requirements on the stent, such as flexibility required for ease of advancing the stent to the stenting site.

In another preferred embodiment, the meander-shaped rings comprise a zig-zag shape. The zig-zag shape of the rings offers good radial elasticity of the tubular structure. Upon release of a self-expanding tubular structure out of an outer confining sheath, the zig-zag shape can relax to an expanded diameter. Along with this expansion goes improved flexibility of the tubular structure against the radially inwardly directed pressure from the surrounding bodily tissue in the installed configuration of the structure.

According to the second aspect of the present invention, there is provided a method of manufacturing a tubular radially expansible metal structure, the method comprising the steps of:

forming a plurality of expansible rings so that the rings are arranged adjacent one another along the longitudinal axis of the structure, and that each of the rings define at least one bridge end;

linking each of the rings with at least one adjacent ring by a bridge extending between adjacent bridge ends on adjacent rings;

characterised by the step of

providing the bridges with an electrical conductivity break between each ring and its adjacent ring, throughout the length of the tubular structure.

Further embodiments of this method are subject of dependent claims 19 and 20.

According to a third aspect of the invention, there is provided a medical guidewire exhibiting at its distal end portion a plurality of conductivity breaks spaced along the length of the distal end portion at intervals of not more than 20 cm

For a better understanding of the present invention, and to show more clearly how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a view from the side of a tubular self-expanding stent structure, looking along a line which intersects the long axis of the tube and is perpendicular to it, the stent being in its larger radius deployed configuration;

Fig. 2 is a perspective view of two meander-shaped rings and showing at respective ends of the meander-shaped rings male and female form-fitting portions to be connected with each other;

Fig. 3 is a perspective view of the two connected meander-shaped rings shown in Fig. 2;

Fig. 4 is a perspective view of two connected meander-shaped rings and showing complementary male and female form-fitting portions according to a preferred embodiment of the invention.

Fig. 5 is a perspective view of two connected meander-shaped rings and showing complementary mating portions according to a preferred embodiment of the invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Skilled readers will appreciate that the stent cylinder can be formed from seamless tubular material, or from flat sheet material rolled into a seamed tube.

Skilled readers will also be well aware that there have been a very large number of proposals for strut patterns in the tubular configurations of stents. Whereas Fig. 1 shows an expandable strut pattern in a form which is particularly preferred for the present invention, nevertheless any of the well known strut patterns will have points at intermediate portions of the stent cylinder where individual meander-shaped rings can be attached to one another.

Fig. 1 shows a stent cylinder in the large radius configuration. As can be seen in Fig. 1, the stent cylinder 2 is constituted by a succession of struts which zig-zag their

way around the full circumference of each individual ring 4. There is a vertex 12 where two successive struts intersect, and at some of which successive meander-shaped rings 4 are joined. Albeit Fig. 1 shows a stent cylinder with flared ends 6 for better anchorage of the stent cylinder inside a body vessel, the present invention is not intended to be limited to stents with flared ends.

In the illustrated embodiment, the stent is made from Nitinol®, a nickel-titanium shape memory alloy. In other embodiments, the stent could be made of stainless steel, or any other biologically compatible conducting material capable of performing a stenting function.

It is conventional to form the lattice pattern of Nitinol® stents by laser-cutting. The line of action of a laser for cutting the frusto-conical mating surfaces of the body portion of the stent are achieved by aligning the laser in the normal, i.e. radial direction, thus intersecting the long axis of the stent tube. Once the slits in the workpiece of the stent tube are cut, most but not all of the vertices axially connecting two adjacent rings of the stent tube are severed, and only a few 12 remain connected in order to maintain an integral tubular stent structure. The smaller the number of connected vertices, the greater the potential the stent has to bend out of a straight line as it is advanced along a tortuous path to the site of stenting. In addition, the flexibility of the stent after deployment is increased as well.

As can be seen in Fig. 1, the bridges 12 connecting two adjacent vertices 12A, 12B at two ends of a stent ring 4 facing each other, have a non-zero length, which, in turn, renders the overall structure in a radially compressed configuration more flexible, so that it can be more easily advanced along a tortuous path within a body lumen.

Turning now to Fig. 2, it is shown in more detail how individual rings 4 of the stent tube 2 are connected with one another. In contrast to Fig. 1, the stent cylinder is shown in its radially compact disposition. In particular, attention is drawn to the constructional details of the connection points 12, i.e. the bridges connecting two adjacent rings. Fig. 2 illustrates two meander-shaped rings 4, which comprise protruding portions 12A, 12B at both axial ends of each of the rings 4. All of the protruding portions exhibit a straight portion 14 provided for enhancing axial flexibility of the stent tube.

The protruding portions can be classified into male portions having an arcuate head portion 12A and female portions having an arcuate recess portion 12B. The female portions comprise rebated internal abutment surfaces to receive the complementary arcuate male head portion. Both male and female portions are frusto-conically shaped due to the laser-cutting process, as described previously. Thus, due to the complementary-shaped male and female portions, they represent a form-fit when connected together which gives the male and female portions excellent attachment security and the bridges are thus self-centering and self-aligning.

Furthermore, the luminal and abluminal major surfaces, out of which the arcuate head portion and the arcuate recess portion are formed, share the same radius of curvature as the major surfaces of the meander-shaped rings. This, however, is not necessarily the case when the stent cylinder is initially laser-cut from flat sheet material.

The number of these mating male and female portions on adjacent meander-shaped rings is not limited to the number shown in Fig. 2. The ratio of mating portions to voids, i.e. points at axial ends of the rings at which the protruding portions are cut-off during the laser-cutting process, can be as much as 1 to 5, or even 1 to 6. It goes without saying

that the number of male portions corresponds to the number of female portions. The number, however, can be readily changed during manufacture of the stent tube.

It has been found that heat generated during the laser-cutting process oxidises part of the metal surface of both male and female form-fitting portions, so that both portions are electrically insulated from one another in the assembled state. This oxide layer provides an electrical conductivity break that is effective to improve MRI-imaging of the stent lumen.

The skilled reader will appreciate that other or additional ways of providing a conductivity break intermediate between the two mating portions of two adjacent rings are conceivable, such as immersing either one or both of the mating portions into an oxidising agent or radiating one or both of the mating portions with a laser, thereby generating sufficient heat to oxidise their metal surfaces. It is conceivable that the naturally occurring oxide layer on the surface of the metal stent might be sufficient for providing the conductivity break.

The thickness of the oxide layer depends on the time period and the intensity of the laser used for radiating one of the mating portions. The thickness of this oxide layer should be sufficient that, when the current induced by the external magnetic field exceeds a certain level, a current-breakthrough between two adjacent rings does not occur, so that the quality of the MRI-image of the stent tube will not be deteriorated by artefacts.

The skilled reader will also appreciate that other ways of connecting two adjacent rings are conceivable. Those alternatives include plug-and-socket type connections, spigot-shoulder type connections, bolt-sleeve type connections, clamped arrangements, glue-type connections,

hinge-type connections which further enhance axial flexibility of the stent tube, thread-eyelet type connections in which a thread is fed through respective eyelets at axial ends of the rings and subsequently, the two ends of the thread are knotted to the eyelets of the rings for holding the rings together, etc.

When inserting the male form-fitting portion into the female form-fitting portion, these two portions stay together upon radial expansion of the stent tube solely due to their complementary form-fit. The male portion is inserted into the female portion radially inwardly due to their radially tapered shape, so that upon radial expansion of the stenting rings, the female portion can push the male portion radially outwardly, thereby pressing the male head portion further inwardly into the female recess portion against the rebated internal abutment surface of the female portion. Friction between the complementary male and female portions may help to improve the rigidity of the connection.

Looking at Figure 2, and a system in which a self-expanding stent is released by proximal withdrawal of a surrounding sheath, sheath withdrawal from left to right in Fig. 2 would allow release of the stenting rings one at a time. Conversely, sheath withdrawal from right to left will keep the stenting rings held together.

A biocompatible adhesive may be used to permanently attach two adjacent rings with one another. If the biocompatible adhesive is moreover non-conductive, the extra oxide layer created by, e.g. immersing at least one of the ends of the two complementary form-fitting portions into an oxidising agent, may be omitted.

Turning now to Figure 3, the two stenting rings are illustrated in the assembled state. As can be seen, the two male and female complementary form-fitting portions are

snugly fitting together with the conductivity break in between. The luminal surface of the bridges 12 is flush with the luminal surface of the stenting rings. This, however, is not crucial for carrying the inventive concept into effect. The luminal surface of the bridges may well be located radially inwardly with respect to the luminal surface of the stenting rings. However, in order to provide unobstructed fluid flow through the stent lumen, the luminal surfaces of the bridges should preferably be flush with the luminal surfaces of the rings.

Figure 4 shows two connected stenting rings with male and female complementary form-fitting portions forming the bridge between two stenting rings according to another preferred embodiment of the invention. The female form-fitting portion has the shape of a fork 12B receiving the male form-fitting portion 12A within the recess in the centre of the fork. Due to the laser cutting process, both male and female form-fitting portions are frusto-conically shaped. There is a gap between the male and female form-fitting portion, the size of which essentially corresponds to the dimension of the laser beam focus. This gap accounts for enhanced flexibility of this type of structure. As can be seen from figure 4, a through-hole extends through the male and female form-fitting portions such that both through-holes are in line in order to allow a pin (not shown) to be inserted therethrough for fixation of the male form-fitting portion to the female form-fitting portion. The through-holes can also be created by a laser beam drill, either under manual control under a microscope, or automatically under microprocessor control.

Figure 5 shows another preferred embodiment of the invention. Two stenting rings are connected via two complementary mating portions both of which are complementary in shape and have a through-hole through which the pin can be inserted for connecting the two stenting rings. Again, due to the laser beam focus having a finite width, a gap remains between the

two complementary portions when connected, so that the connection allows a certain degree of pivotal movement when the stent tube is advanced along a tortuous path inside a body vessel. Each hinge pin 14 may be spot-welded to the respective ends of the two complementary mating portions, may be glued thereto, or may be fixed in some other way.

In order to complete the entire stent cylinder, a plurality of such stenting rings is connected in series. Since every bridge comprises an electrical conductivity break, there is no electrical connection running from one end of the stent cylinder to the other. All connections between adjacent rings are substantially electrically non-conductive for achieving the desired effect, so that, when the stent cylinder is exposed to an HF-signal in a MRI-imaging apparatus, it is reasonable to assume that no electrical currents will flow from one end of the stent cylinder to the other end of the stent cylinder. Any currents induced in the stent cylinder due to the magnetic field associated with the HF-signal are thought to be confined within each of the rings, thus ameliorating the adverse effect of artefacts on the MRI-image of the stent lumen.

Once the stent cylinder is completed by connecting a plurality of such stenting rings in series, and the stent cylinder is confined within an outer sheath ready for deployment, the structure of the stent cylinder, and in particular the structure of the bridges, according to one preferred embodiment, as shown in Fig. 3, allows placement of individual stenting rings at spaced apart locations inside a body vessel. This is accomplished by gradually moving the outer sheath proximally by an amount equal to the axial length of one stenting ring. This enables the medical practitioner to release only one stenting ring at a time so that individual stenting rings can be placed at different locations within the lumen of a body vessel. It is clear to the skilled person that the structure of the bridge has to be

such that one stenting ring can separate itself from its neighbouring stenting ring whilst the neighbouring stenting ring is still confined within the outer sheath.

The skilled person will appreciate that, although the invention is primarily directed to tubular radially expansible structures, such as stents, it may also be applied to guide wires used in catheter-based surgery. Such guide wires may also be provided with dielectric or non-conductive intermediate portions along the actual length of the guide wire. It is thought that providing a conductivity break at least every 20cm along the distal part of the guidewire length will allow the guidewire to merit the designation "MRI-compatible".

The scope of protection of the claims which follow is not to be limited to the embodiments described in detail above. Readers will appreciate that the detailed description is to assist the skilled reader in realising embodiments within the scope of the claims rather than to set a limit on the scope of protection.

Claims:

1. A tubular radially expansible metal structure (2) having an abluminal wall, a luminal wall and a radial wall thickness therebetween, with struts defining through-apertures in the wall, the structure further having a longitudinal axis and defining a plurality of expansible rings (4) arranged adjacent one another along the longitudinal axis of the structure, each of the rings (4) defining at least one bridge end (12A, 12B) and adjacent rings being linked by a bridge (12) extending between adjacent bridge ends (12A, 12B) on adjacent rings (4),

   characterised in that

   said bridges (12) comprise an electrical conductivity break between each ring (4) and its adjacent ring (4), throughout the length of the tubular structure (2).

2. The structure according to claim 1, wherein the bridge (12) comprises inter-engaged joint portions which allow a degree of relative pivotal movement.

3. The structure according to claims 1 or 2, wherein the bridge (12) comprises complementary mating portions (12A, 12B).

4. The structure according to claim 3, wherein the mating portions are male-female form-fitting portions.

5. The structure according to claim 4, wherein the form-fitting portions have a frusto-conical shape.

6. The structure according to claims 4 or 5, wherein the male form-fitting portion comprises a mating head portion having an arcuate end surface, and the female

form-fitting portion comprises a mating arcuate end portion with a rebated internal abutment surface to receive the arcuate head portion.

7. The structure according to any one of claims 3 to 6, wherein at least one of the mating portions carries a biocompatible adhesive for enhancing the rigidity of the bridge.

8. The structure according to any one of the preceding claims, wherein the electrical conductivity break is a layer which interrupts electrical conductivity.

9. The structure according to one of claims 3 to 8, wherein the conductivity break comprises a conductivity interrupting layer on an abutment surface of at least one of the complementary mating portions.

10. The structure according to claim 8 or 9, wherein the conductivity interrupting layer is an oxide layer.

11. The structure according to any one of the preceding claims, wherein the length axis of the bridge is not parallel to the longitudinal axis of the structure.

12. The structure according to any one of the preceding claims, wherein the bridge has the shape of a meander.

13. The structure according to any one of the preceding claims, wherein the shape of the bridge resembles that of an "S".

14. The structure according to any one of the preceding claims, wherein the number of bridges is less than the number of meanders in one ring.

15. The structure according to any one of the preceding claims, wherein the structure is made of a nickel titanium shape-memory alloy.

16. The structure according to any one of claims 1 to 14, wherein the structure is made of stainless steel.

17. The structure according to any one of the preceding claims, wherein the structure is a medical stent.

18. A method of manufacturing a tubular radially expansible metal structure, the method comprising the steps of:

forming a plurality of expansible rings so that the rings are arranged adjacent one another along the longitudinal axis of the structure, and that each of the rings define at least one bridge end;

linking each of the rings with at least one adjacent ring by a bridge extending between adjacent bridge ends on adjacent rings;

characterised by the step of

providing the bridges with an electrical conductivity break between each ring and its adjacent ring, throughout the length of the tubular structure.

19. The method according to claim 18, wherein the step of forming the expansible rings includes the steps of:

providing a tubular workpiece;

mounting the tubular workpiece on a support; and

laser-cutting the workpiece to form meanders in rings arranged longitudinally adjacent one another, each having a first end and a second end, and at least one complementary mating portion arranged on said first end of each of said rings to mate with a complementary mating portion on the second end of the adjacent ring.

20. The method according to claim 18 or 19, wherein the step of linking each of the rings with an adjacent ring by at least one bridge includes the steps of:

oxidising abutment surfaces within the bridges, whereby each bridge includes a conductivity interrupting layer which constitutes said conductivity break.

21. A medical metal guidewire,

characterised by

a distal length portion exhibiting a plurality of conductivity breaks spaced along the length of the portion at intervals of not more than 20 cm.

ABSTRACT

The present invention relates to tubular radially expansible metal structures having an abluminal wall, a luminal wall and a radial wall thickness therebetween, with struts defining through-apertures in the wall, the structure further having a longitudinal axis and defining a plurality of expansible rings arranged adjacent one another along the longitudinal axis of the structure, each of the rings defining at least one bridge end, and adjacent rings being linked by a bridge extending between adjacent bridge ends on adjacent rings, the tubular structure being characterised in that the bridges comprise an electrical conductivity break between each ring and its adjacent ring, throughout the length of the tubular structure. The present invention relates furthermore to a method of manufacturing such a tubular structure, and a medical guidewire exhibiting at its distal end portion a plurality of conductivity breaks spaced along the length of the distal end portion at intervals of not more than 20 cm.

(Fig. 2)

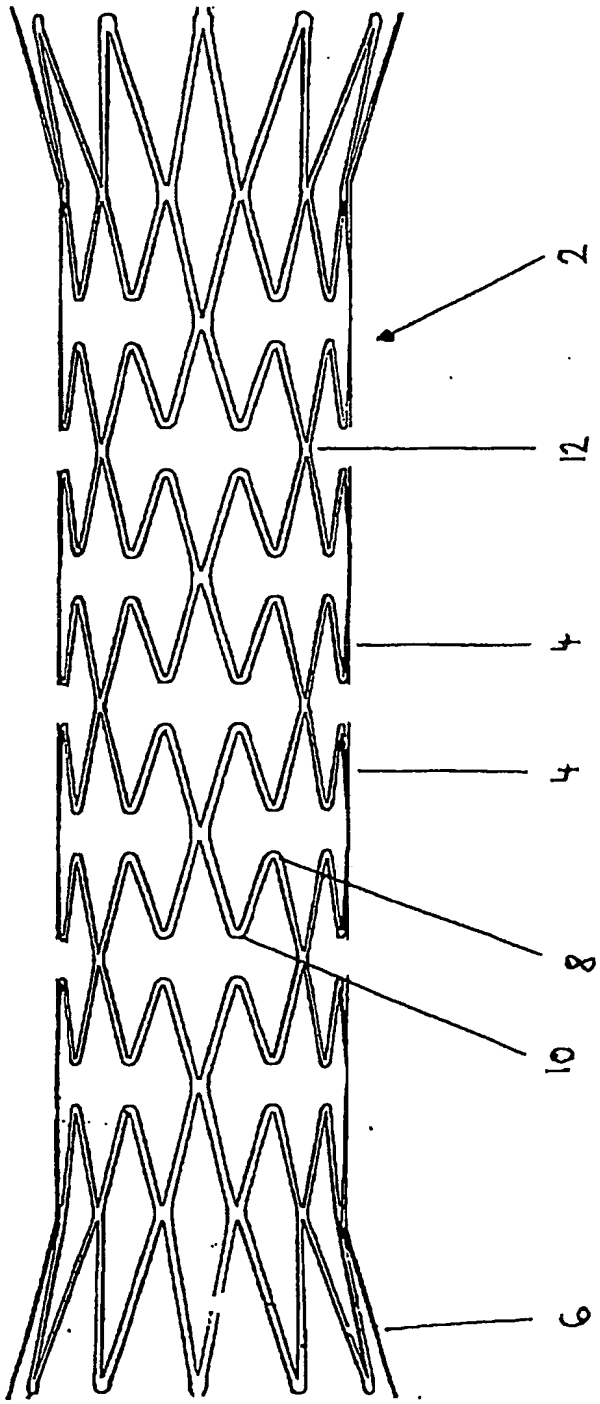

Fig. 1

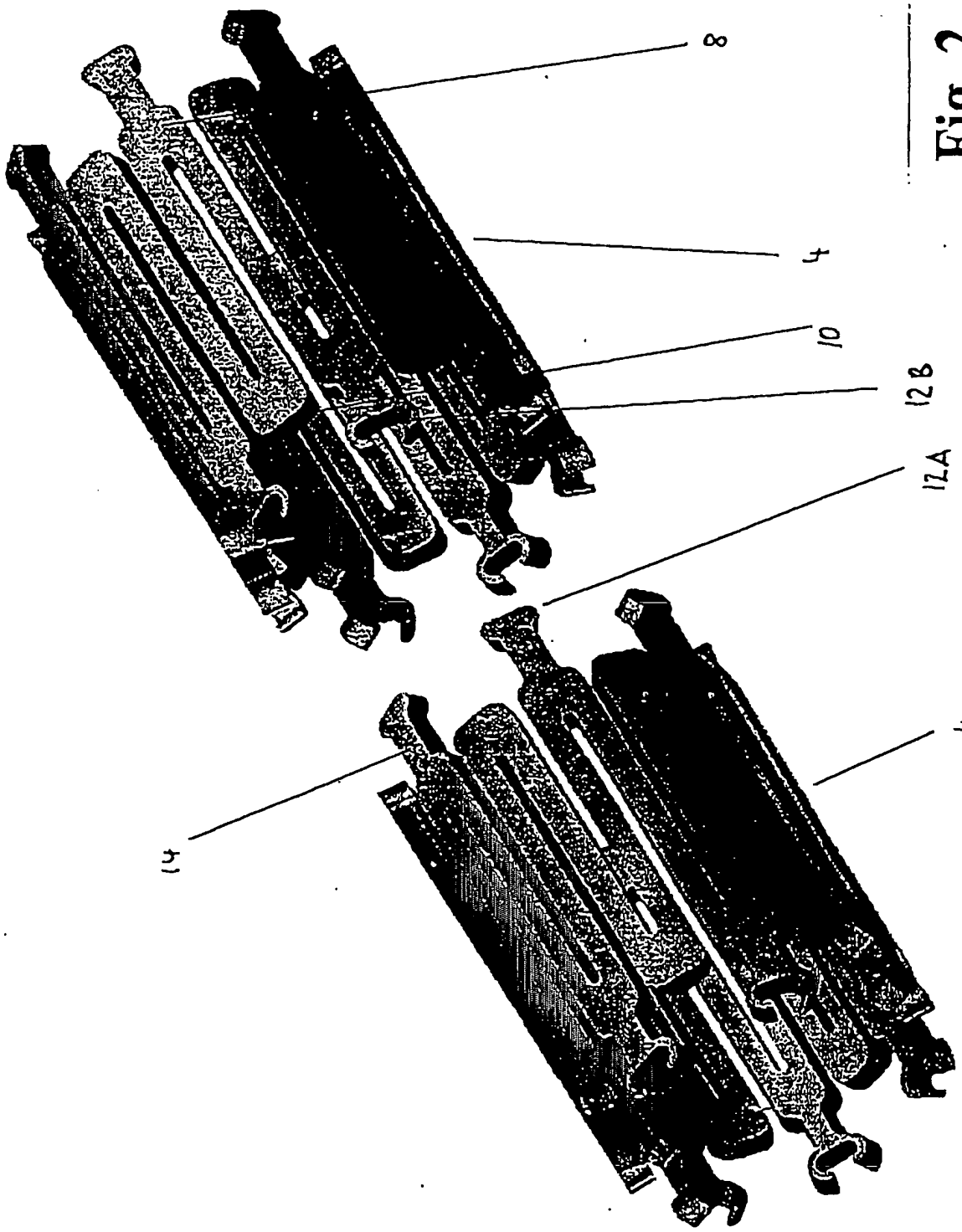

Fig. 2

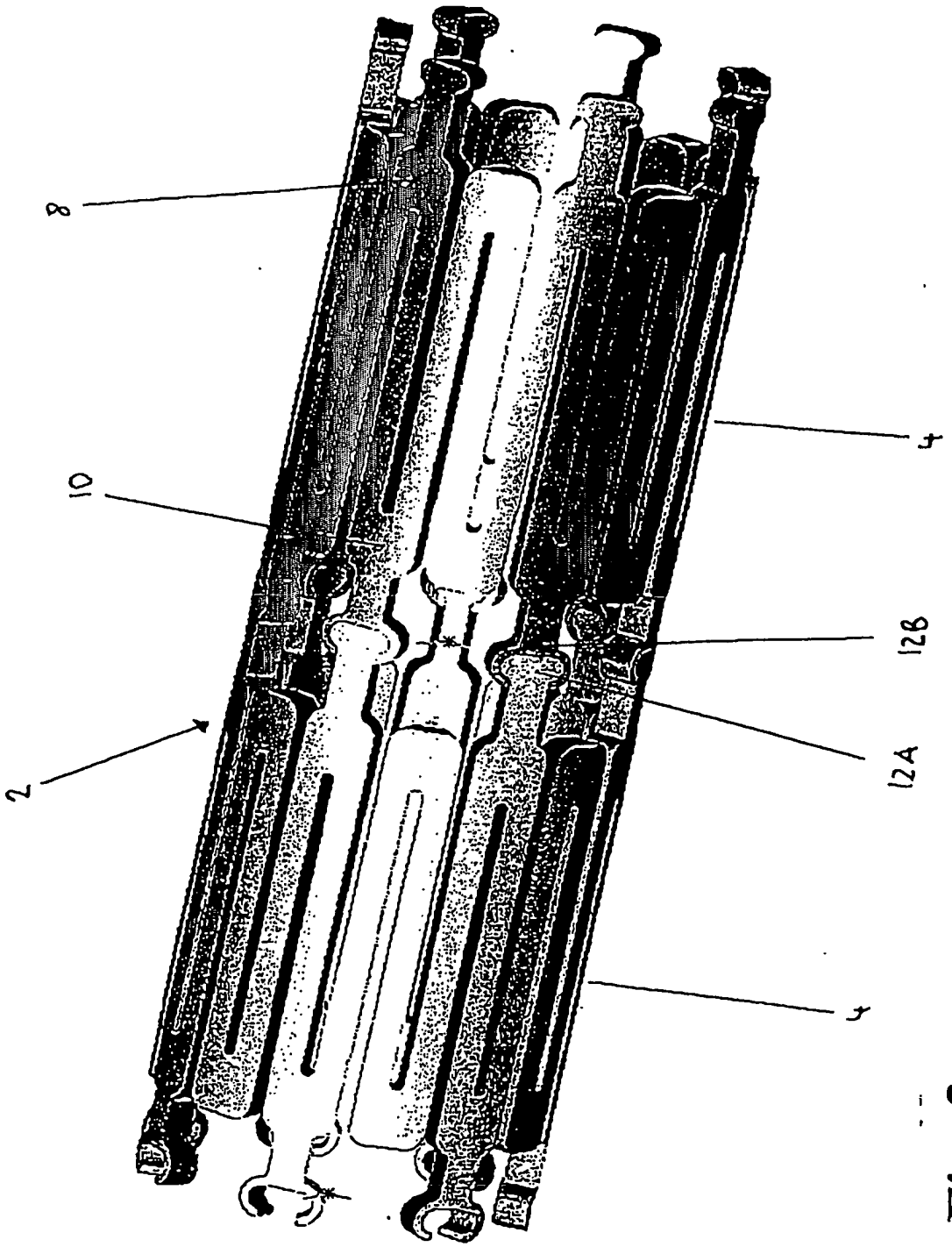

Fig. 3

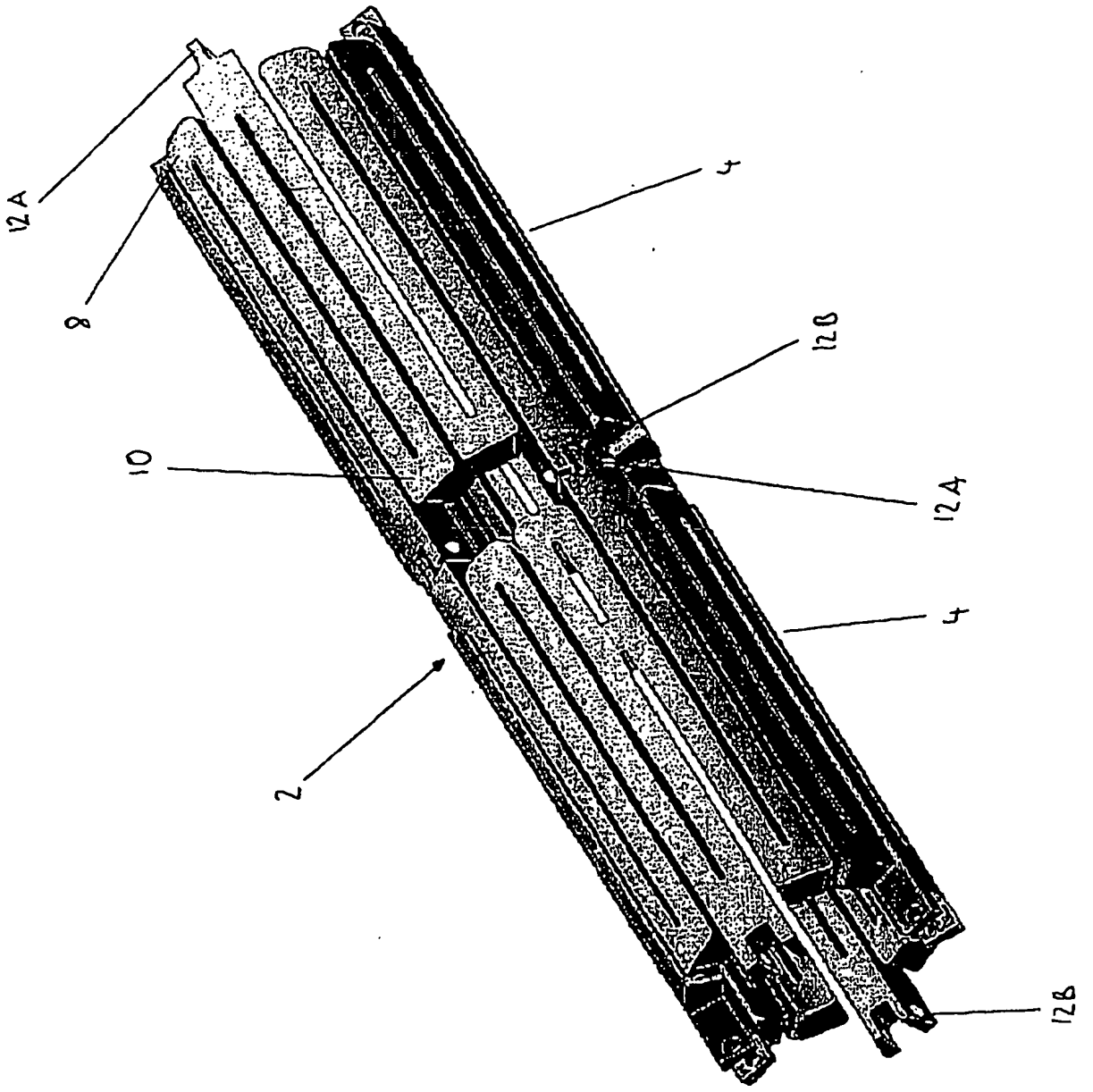

Fig. 4

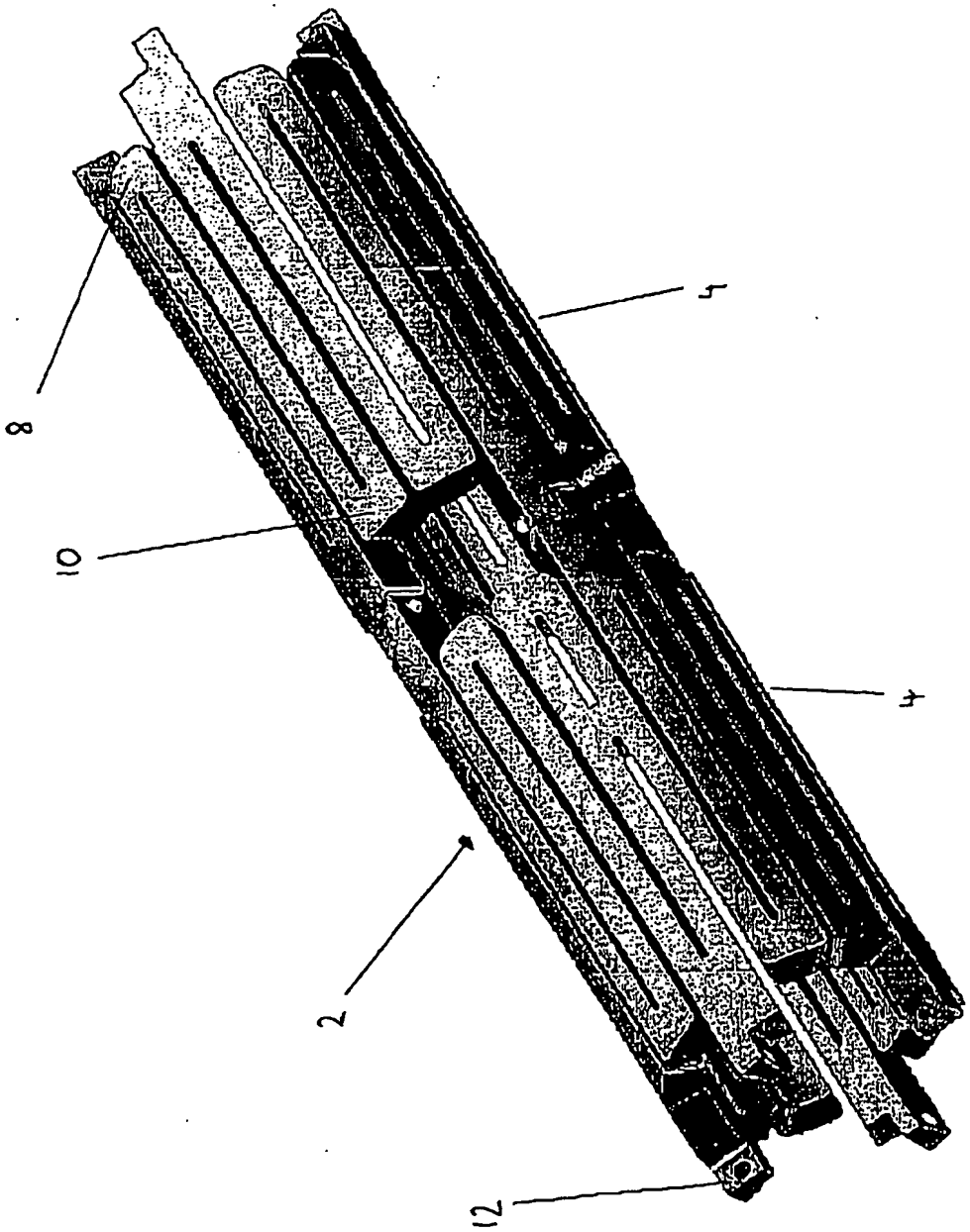

Fig. 5